# **Complete Summary**

### **GUIDELINE TITLE**

Cryptorchidism. In: Guidelines on paediatric urology.

# **BIBLIOGRAPHIC SOURCE(S)**

Cryptorchidism. In: Tekgül S, Riedmiller H, Gerharz E, Hoebeke P, Kocvara R, Nijman R, Radmayr Chr, Stein R. Guidelines on paediatric urology. Arnhem, The Netherlands: European Association of Urology, European Society for Paediatric Urology; 2009 Mar. p. 8-11. [16 references]

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Cryptorchidism. In: Tekgül S, Riedmiller H, Gerharz E, Hoebeke P, Kocvara R, Nijman R, Radmayr C, Stein R. Guidelines on paediatric urology. Arnhem, The Netherlands: European Association of Urology, European Society for Paediatric Urology; 2008 Mar. p. 9-11.

# **COMPLETE SUMMARY CONTENT**

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**SCOPE** 

## DISEASE/CONDITION(S)

Cryptorchidism

# **GUIDELINE CATEGORY**

Diagnosis Screening Treatment

## **CLINICAL SPECIALTY**

Pediatrics Surgery Urology

## **INTENDED USERS**

Physicians

# **GUIDELINE OBJECTIVE(S)**

- To outline a practical and preliminary approach to paediatric urological problems
- To increase the quality of care for children with urological problems

## **TARGET POPULATION**

Male infants and children with cryptorchidism

## INTERVENTIONS AND PRACTICES CONSIDERED

# **Diagnosis**

- 1. Physical examination for palpable vs nonpalpable testes with and without anesthesia
- 2. Diagnostic laparoscopy
- 3. Endocrinology and genetic referral in some cases

# Treatment

- 1. Medical therapy: human chorionic gonadotropin (hCG), gonadotrophin-releasing hormone (GnRH)
- 2. Surgery for palpable testis, orchidofuniculolysis, orchidopexy
- 3. Surgery for non-palpable testis: inguinal surgical exploration, laparoscopic removal or orchidolysis and orchiopexy, Fowler–Stephens procedure, timing of 2-step procedure, microvascular autotransplantation

# Follow-up

- 1. Testicular cancer screening during and after puberty
- 2. Follow-up of retractile testes until puberty

## **MAJOR OUTCOMES CONSIDERED**

- Rate of spontaneous testicular descent
- Testicular survival rate after surgery
- Fertility rate
- Paternity rate
- Incidence and prevalence of testicular malignancy

## **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

# **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

The guidelines were based on current literature following a systematic review using MEDLINE.

# **NUMBER OF SOURCE DOCUMENTS**

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

# Levels of EvidenceÂ

- **1a** Evidence obtained from meta-analysis of randomized trials
- **1b** Evidence obtained from at least one randomized trial
- **2a** Evidence obtained from at least one well-designed controlled study without randomization
- **2b** Evidence obtained from at least one other type of well-designed quasi-experimental study
- **3** Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports
- **4** Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Application of a structured analysis of the literature was not possible due to a lack of well-designed studies. Whenever possible, statements have been classified in

terms of level of evidence and grade of recommendation. Due to the limited availability of large randomized controlled trials – influenced also by the fact that a considerable number of treatment options relate to surgical interventions on a large spectrum of different congenital problems – this document is therefore largely a consensus document.

### METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

- The first step in the European Association of Urology (EAU) guidelines procedure is to define the main topic.
- The second step is to establish a working group. The working groups comprise about 4-8 members, from several countries. Most of the working group members are academic urologists with a special interest in the topic. In general, general practitioners or patient representatives are not part of the working groups. A chairman leads each group. A collaborative working group consisting of members representing the European Society for Paediatric Urology (ESPU) and the EAU has gathered in an effort to produce the current update of the paediatric urology guidelines.
- The third step is to collect and evaluate the underlying evidence from the published literature.
- The fourth step is to structure and present the information. The strength of the recommendation is clearly marked in three grades (A-C), depending on the evidence source upon which the recommendation is based. Every possible effort is made to make the linkage between the level of evidence and grade of recommendation as transparent as possible.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

## Grades of RecommendationÂ

- A. Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomized trial
- B. Based on well-conducted clinical studies, but without randomized clinical studies
- C. Made despite the absence of directly applicable clinical studies of good quality

#### **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

# **METHOD OF GUIDELINE VALIDATION**

Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

There is no formal external review prior to publication.

The Appraisal of Guidelines for Research and Evaluation (AGREE) instrument was used to analyse and assess a range of specific attributes contributing to the validity of a specific clinical guideline.

The AGREE instrument, to be used by two to four appraisers, was developed by the AGREE collaboration (<a href="www.agreecollaboration.org">www.agreecollaboration.org</a>) using referenced sources for the evaluation of specific guidelines. (See the "Availability of Companion Documents" field for further methodology information).

## **RECOMMENDATIONS**

### **MAJOR RECOMMENDATIONS**

Levels of evidence (1a-4) and grades of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

# **Background**

Retractile testes do not need any form of treatment except observation as they can become ascendant. Retractile testes have completed their descent but may be found in the groin because of a strong cremasteric reflex.

In the case of bilateral non-palpable testes and any suggestion of sexual differentiation problems, such as hypospadias, urgent endocrinological and genetic evaluation is mandatory (**level of evidence: 3; grade of recommendation B**).

## **Diagnosis**

A physical examination is the only method of differentiating between palpable or non-palpable testes. There is no additional benefit in performing ultrasound, computed tomography (CT), magnetic resonance imaging (MRI) or angiography.

Clinical examination includes a visual description of the scrotum and an examination of the child while supine and in crossed-leg position. The examiner should inhibit the cremasteric reflex with his non-dominant hand right above the symphysis in the groin region before touching, or reaching for, the scrotum. The groin region may be 'milked' towards the scrotum in an attempt to move the testis into the scrotum. This manoeuvre also makes it possible to differentiate between an inguinal testis and enlarged lymph nodes, which can give the impression of an undescended testis.

A retractile testis can generally be brought into the scrotum, where it will remain until a cremasteric reflex (touching the inner thigh skin) will retract it again into the groin.

A unilateral, non-palpable, testis and an enlarged, contralateral, testis may suggest testicular absence or atrophy, but this finding is not specific and does not preclude surgical exploration. In the case of an inquinal, non-palpable testis, a

careful visual inspection should be made of the femoral, penile and perineal region to exclude an ectopic testis.

There is no reliable examination to confirm or rule out an intra-abdominal, inguinal and absent/vanishing testis (non-palpable testis), except for diagnostic laparoscopy (**level of evidence: 1b; grade of recommendation A**). Before carrying out a laparoscopic assessment, an examination under general anaesthesia is recommended because some, originally non-palpable, testes are palpable under anaesthetic conditions.

### Treatment

If a testis has not descended by the age of 1 year, there is no benefit in waiting for a spontaneous descent. To prevent histological deterioration, treatment should be carried out and finished before 12-18 months of age.

# **Medical Therapy**

Medical Therapy for Testicular Descent

Medical therapy using human chorionic gonadotrophin (hCG) or gonadotrophin-releasing hormone (GnRH) is based on the hormonal dependence of testicular descent, with success rates of a maximum of 20% (**level of evidence: 1, grade of recommendation: C**). Hormonal therapy for testicular descent has lower success rates the higher the undescended testis is located. hCG is given in a total dosage of 6.000 to 9.000 units, given in four doses within 2 to 3 weeks, depending on weight and age and GnRH in a dosage of 1.2 mg/day, divided into three dosages per day, for 4 weeks using a nasal spray, respectively.

Medical Therapy for Fertility Potential

Medical treatment can be beneficial before (dosage as described above) or after (low intermittent dosages) surgical orchidolysis and orchidopexy in terms of increasing the fertility index, which may act as a predictor of fertility later in life (level of evidence: 1b; grade of recommendation: A). However, data from the long-term follow-up of the impact of hormonal treatment on fertility potential are still lacking.

### Surgery

## Palpable Testis

Surgery for the palpable testis includes orchidofuniculolysis and orchidopexy, via an inguinal approach, with success rates of up to 92%. It is important to remove and dissect all cremasteric fibres to prevent secondary retraction. Associated problems, such as an open processus vaginalis, must be carefully dissected and closed. It is recommended that the testis is placed in a subdartos pouch. With regard to sutures, there should either be no fixation sutures or they should be made between the tunica vaginalis and the dartos musculature.

The lymph drainage of a testis that has undergone surgery for orchidopexy has been changed from iliac drainage to iliac and inguinal drainage (which is important in the event of later malignancy).

## Non-palpable Testis

In the situation of a non-palpable testis, inguinal surgical exploration with the possibility of performing laparoscopy should be attempted. There is a significant chance of finding the testis via an inguinal incision, but in rare cases, it is necessary to search into the abdomen if there are no vessels or vas deferens in the groin. Laparoscopy is the most appropriate way of examining the abdomen for a testis. In addition, either removal or orchidolysis and orchiopexy can be performed via laparoscopic access. Before starting diagnostic laparoscopy it is recommended that the child be examined again under general anaesthesia because a previously non-palpable testis might now be palpable under anaesthetic conditions.

An intra-abdominal testis in a 10-year-old boy or older with a normal contralateral testis should be removed. In bilateral intra-abdominal testes, or in a boy younger than 10 years, a one-stage or two-stage Fowler-Stephens procedure can be performed. In the event of a two-stage procedure, the spermatic vessels are either laparoscopically clipped or coagulated proximal to the testis to allow development of collateral vasculature. The second-stage procedure, in which the testis is brought directly over the symphysis and next to the bladder into the scrotum, can also be performed by laparoscopy 6 months later. The testicular survival rate in a one-stage procedure varies between 50% and 60%, with success rates rising up to 90% in a two-stage procedure. Microvascular autotransplantation can also be performed with 90% testicular survival rate. However, the procedure requires a very skilful and experienced surgical technique.

# **Prognosis**

Boys with one undescended testis have a lower fertility rate, but the same paternity rate as boys with bilateral descended testes. Boys with bilateral undescended testes have both lower fertility and paternity rates.

Boys with an undescended testis have a 20-fold higher chance of developing testicular malignancy, a risk which is uninfluenced by any kind of treatment. Screening both during and after puberty is therefore recommended for these boys. A systematic literature review and meta-analysis by an American group has concluded that prepubertal orchiopexy may decrease the risk of testicular cancer and that early surgical intervention is indicated in children with cryptorchidism.

Boys with retractile testes do not need medical or surgical treatment but require close follow-up until puberty.

Due to the lack of spontaneous testicular descent after the age of 1 year, and because of the potential loss of testicular quality, it is recommended that surgical orchidolysis and orchidopexy are performed at the latest by 12-18 months of age. To date, it seems that either pre- or post-operative hormonal treatment may have a beneficial effect on fertility later in life.

# **Definitions:**

## **Levels of Evidence**

- **1a** Evidence obtained from meta-analysis of randomized trials
- **1b** Evidence obtained from at least one randomized trial
- **2a** Evidence obtained from at least one well-designed controlled study without randomization
- **2b** Evidence obtained from at least one other type of well-designed quasi-experimental study
- **3** Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports
- **4** Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

## **Grades of Recommendation**

- A. Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomized trial
- B. Based on well-conducted clinical studies, but without randomized clinical studies
- C. Made despite the absence of directly applicable clinical studies of good quality

## **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for some of the recommendations (see the "Major Recommendations" field).

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## **POTENTIAL BENEFITS**

- Appropriate/timely diagnosis and treatment of cryptorchidism
- Improved fertility
- Reduction in the risk of testicular malignancy

## **POTENTIAL HARMS**

# **QUALIFYING STATEMENTS**

## **QUALIFYING STATEMENTS**

The purpose of these texts is not to be proscriptive in the way a clinician should treat a patient but rather to provide access to the best contemporaneous consensus view on the most appropriate management currently available. European Association of Urology (EAU) guidelines are not meant to be legal documents but are produced with the ultimate aim to help urologists with their day-to-day practice.

## **IMPLEMENTATION OF THE GUIDELINE**

## **DESCRIPTION OF IMPLEMENTATION STRATEGY**

The European Association of Urology (EAU) Guidelines long version (containing all 19 guidelines) is reprinted annually in one book. Each text is dated. This means that if the latest edition of the book is read, one will know that this is the most updated version available. The same text is also made available on a CD (with hyperlinks to PubMed for most references) and posted on the EAU websites Uroweb and Urosource (<a href="www.uroweb.org/professional-resources/guidelines/">www.uroweb.org/index.php?id=388</a>).

Condensed pocket versions, containing mainly flow-charts and summaries, are also printed annually. All these publications are distributed free of charge to all (more than 10,000) members of the Association. Abridged versions of the guidelines are published in European Urology as original papers. Furthermore, many important websites list links to the relevant EAU guidelines sections on the association websites and all, or individual, guidelines have been translated to some 15 languages.

## **IMPLEMENTATION TOOLS**

Foreign Language Translations Pocket Guide/Reference Cards Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### **IOM CARE NEED**

Getting Better Staying Healthy

## **IOM DOMAIN**

Effectiveness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

# **BIBLIOGRAPHIC SOURCE(S)**

Cryptorchidism. In: Tekgül S, Riedmiller H, Gerharz E, Hoebeke P, Kocvara R, Nijman R, Radmayr Chr, Stein R. Guidelines on paediatric urology. Arnhem, The Netherlands: European Association of Urology, European Society for Paediatric Urology; 2009 Mar. p. 8-11. [16 references]

## **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

## **DATE RELEASED**

2008 Mar (revised 2009 Mar)

# **GUIDELINE DEVELOPER(S)**

European Association of Urology - Medical Specialty Society European Society for Paediatric Urology - Medical Specialty Society

# **SOURCE(S) OF FUNDING**

European Association of Urology

## **GUIDELINE COMMITTEE**

Not stated

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: S. Tekgül (Co-chairman); H. Riedmiller (Co-chairman); E. Gerharz; P. Hoebeke; R. Kocvara; R. Nijman; Chr. Radmayr; R. Stein

# FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Paediatric Urology Guidelines writing panel have provided disclosure statements on all relationships that they have and that might be perceived to be a potential source of conflict of interest. This information is kept on file in the European Association of Urology Central Office database. This guidelines document was developed with the financial support of the European Association of Urology (EAU). No external sources of funding and support have been involved. The EAU is a non-profit organisation and funding is limited to administrative assistance and travel and meeting expenses. No honoraria or other reimbursements have been provided.

## **GUIDELINE STATUS**

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This guideline updates a previous version: Cryptorchidism. In: Tekgül S, Riedmiller H, Gerharz E, Hoebeke P, Kocvara R, Nijman R, Radmayr C, Stein R. Guidelines on paediatric urology. Arnhem, The Netherlands: European Association of Urology, European Society for Paediatric Urology; 2008 Mar. p. 9-11.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the <u>European Association of Urology Web site</u>.

Print copies: Available from the European Association of Urology, PO Box 30016, NL-6803, AA ARNHEM, The Netherlands.

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- Guidelines on paediatric urology. Pocket guideline. Arnhem, The Netherlands: European Association of Urology (EAU); 2009 Mar. 13 p. Electronic copies: Available in <u>English</u> and <u>Russian</u> in Portable Document Format (PDF) from the European Association of Urology Web site. Also available as an e-book form the <u>European Association</u> of <u>Urology Web site</u>.
- EAU guidelines office template. Arnhem, The Netherlands: European Association of Urology (EAU); 2007. 4 p.
- The European Association of Urology (EAU) guidelines methodology: a critical evaluation. Arnhem, The Netherlands: European Association of Urology (EAU); 18 p.

Print copies: Available from the European Association of Urology, PO Box 30016, NL-6803, AA ARNHEM, The Netherlands.

## **PATIENT RESOURCES**

None available

# **NGC STATUS**

This NGC summary was completed by ECRI Institute on November 14, 2008. The information was verified by the guideline developer on December 19, 2008. This NGC summary was updated by ECRI Institute on November 13, 2009. The information was verified by the guideline developer on December 23, 2009.

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